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- PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION) MDL Docket No. 1699
)
This document relates to) CASE NO. 3:08-cv-1749-CRB
)
GARY W. BROWN, et al.,) PFIZER INC., PHARMACIA
) CORPORATION, AND G.D.
) SEARLE LLC'S ANSWER TO
) COMPLAINT
)
Plaintiffs,) JURY DEMAND ENDORSED
) HEREIN
)
vs.)
)
PFIZER, INC., PHARMACIA CORPORATION,)
and G.D. SEARLE, LLC,)
)
Defendants.)

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC (improperly captioned in Plaintiffs' Complaint as "G.D. Searle, LLC") ("Searle") (collectively "Defendants"), and file this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

L.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used Celebrex® (celecoxib) (“Celebrex®”). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiffs were prescribed and used Celebrex®.

II.

ANSWER

1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but
deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain
periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United
States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
accordance with their approval by the FDA. Defendants admit that, during certain periods of
time, Celebrex® was manufactured and packaged for Searle, which developed, tested,
marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by
healthcare providers who are by law authorized to prescribe drugs in accordance with their
approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
in accordance with its FDA-approved prescribing information. Defendants state that the
potential effects of Celebrex® were and are adequately described in its FDA-approved
prescribing information, which was at all times adequate and comported with applicable
standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused
Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the
Complaint.

Response to Allegations Regarding Parties

2 2. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and
4 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
5 paragraph of the Complaint.

6 3. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and
8 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
9 paragraph of the Complaint.

10 4. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and
12 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
13 paragraph of the Complaint.

14 5. Defendants admit that Pfizer is a Delaware corporation with its principal place of
15 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
16 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
17 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
20 that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous.
21 Defendants are without knowledge or information to form a belief as to the truth of such
22 allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this
23 paragraph of the Complaint.

24 6. Defendants admit that Searle is a Delaware limited liability company with its principal
25 place of business in Illinois. Defendants admit that, as the result of a merger in April 2003,
26 Searle became a subsidiary of Pfizer. Defendants admit that, during certain periods of time,
27 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
28 promoted and distributed Celebrex® in the United States to be prescribed by healthcare

1 providers who are by law authorized to prescribe drugs in accordance with their approval by the
2 FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

3 7. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
4 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia
5 marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare
6 providers who are by law authorized to prescribe drugs in accordance with their approval by the
7 FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are
8 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
9 the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining
10 allegations in this Paragraph of the Complaint.

11 **Response to Allegations Regarding Jurisdiction and Venue**

12 8. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and
14 the amount in controversy, and, therefore, deny the same. However, Defendants admit that
15 Plaintiffs claim that the parties are diverse and that the amount in controversy exceeds \$75,000,
16 exclusive of interests and costs.

17 9. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding the judicial district in
19 which the asserted claims allegedly arose, and, therefore, deny the same. Defendants admit
20 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
21 Celebrex® in the United States, including California and Arkansas, to be prescribed by
22 healthcare providers who are by law authorized to prescribe drugs in accordance with their
23 approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
24 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
25 distributed Celebrex® in the United States to be prescribed by healthcare providers who are by
26 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
27 admit that they provided FDA-approved prescribing information regarding Celebrex®.
28 Defendants admit that they do business in the States of California and Arkansas. Defendants

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1 state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous.
2 Defendants are without knowledge or information to form a belief as to the truth of such
3 allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
4 committing a tort in the States of California and Arkansas, and deny the remaining allegations
5 in this paragraph of the Complaint.

6 **Response to Allegations Regarding Interdistrict Assignment**

7 10. Defendants state that this paragraph of the Complaint contains legal contentions to
8 which no response is required. To the extent that a response is deemed required, Defendants
9 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
10 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
11 Panel on Multidistrict Litigation on September 6, 2005.

12 **Response to Factual Allegations**

13 11. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
14 and co-promoted Celebrex® in the United States, including Arkansas, to be prescribed by
15 healthcare providers who are by law authorized to prescribe drugs in accordance with their
16 approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
17 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
18 distributed Celebrex® in the United States to be prescribed by healthcare providers who are by
19 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
20 admit that they provided FDA-approved prescribing information regarding Celebrex®.
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 12. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny
27 the remaining allegations in this paragraph of the Complaint.

28 13. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
2 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny
5 the remaining allegations in this paragraph of the Complaint.

6 14. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
8 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny
11 the remaining allegations in this paragraph of the Complaint.

12 15. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny the remaining the allegations in this paragraph of the Complaint.

17 16. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
18 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
19 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
20 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
21 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
22 Celebrex® in the United States to be prescribed by healthcare providers who are by law
23 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
24 that they provided FDA-approved prescribing information regarding Celebrex®. Defendants
25 deny the remaining allegations in this paragraph of the Complaint.

26 17. Defendants admit that Celebrex® is in a class of drugs that is, at times, referred to as
27 non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendant states that, as stated in the
28 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to

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1 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2
2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the
3 cyclooxygenase-1 (COX-1) isoenzyme.” Defendants admit that Celebrex® was approved by
4 the FDA on December 31, 1998. Defendant states that Celebrex® is a prescription medication
5 which is approved by the FDA for the following indications: (1) for relief of the signs and
6 symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in
7 adults; (3) for the management of acute pain in adults; (4) for the treatment of primary
8 dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
9 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
10 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the
11 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.
12 Defendants deny the remaining allegations in this paragraph of the Complaint.

13 18. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining the allegations in this paragraph
18 of the Complaint.

19 19. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining the allegations in this paragraph of the Complaint.

27 20. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that they provided FDA-approved prescribing information regarding
4 Celebrex®. Defendants deny the remaining the allegations in this paragraph of the Complaint.

5 21. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining the allegations in this paragraph
10 of the Complaint.

11 22. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
18 Celebrex® caused Plaintiffs injury or damages, and deny the remaining the allegations in this
19 paragraph of the Complaint.

20 **Response to First Cause of Action: Products Liability**

21 23. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
22 Complaint as if fully set forth herein.

23 24. Defendants state that this paragraph of the Complaint contains legal contentions to
24 which no response is required. To the extent that a response is deemed required, Defendants
25 are without knowledge or information sufficient to form a belief as to the truth of the
26 allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
4 Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs or
5 Decedents injury or damages, and deny the remaining allegations this paragraph of the
6 Complaint, including all subparts.

7 25. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
9 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
10 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
11 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
14 that they provided FDA-approved prescribing information regarding Celebrex®. Defendants
15 deny the remaining the allegations in this paragraph of the Complaint.

16 26. Defendants admit that Celebrex® was expected to reach consumers without substantial
17 change from the time of sale. Defendants are without knowledge or information sufficient to
18 form a belief as to the truth of the allegations in this paragraph of the Complaint regarding
19 whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that
20 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
21 prescribing information. Defendants state that the potential effects of Celebrex® were and are
22 adequately described in its FDA-approved prescribing information, which was at all times
23 adequate and comported with applicable standards of care and law. Defendants deny any
24 wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining
25 allegations this paragraph of the Complaint.

26 27. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
28 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Celebrex® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
5 Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs
6 injury or damages, and deny the remaining allegations this paragraph of the Complaint.

7 28. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
12 damages, and deny the remaining allegations this paragraph of the Complaint.

13 29. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations this paragraph of
18 the Complaint.

19 30. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations this paragraph of the Complaint.

27 31. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
6 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations this
7 paragraph of the Complaint.

8 32. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations this paragraph of
13 the Complaint.

14 33. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
19 damages, and deny the remaining allegations this paragraph of the Complaint.

20 34. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
21 damages, and deny the remaining allegations this paragraph of the Complaint.

22 35. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex®
27 caused Plaintiffs injury or damages, and deny the remaining allegations this paragraph of the
28 Complaint.

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1 36. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
3 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny
6 the remaining allegations this paragraph of the Complaint.

7 37. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
8 damages, and deny the remaining allegations this paragraph of the Complaint.

Response to Second Cause of Action: Strict Products Liability

10 | 38. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
11 | Complaint as if fully set forth herein.

12 39. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations this paragraph of
17 the Complaint.

18 40. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
19 damages, and deny the remaining allegations this paragraph of the Complaint.

20 41. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
21 damages, and deny the remaining allegations this paragraph of the Complaint.

22 42. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
23 damages, and deny the remaining allegations this paragraph of the Complaint.

Response to Third Cause of Action: Express Warranty

25 43. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
26 Complaint as if fully set forth herein.

27 44. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used

1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants admit that they provided FDA-approved
6 prescribing information regarding Celebrex®. Defendants deny the remaining allegations this
7 paragraph of the Complaint.

8 45. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
10 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
15 remaining allegations this paragraph of the Complaint.

16 46. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
17 damages, and deny the remaining allegations this paragraph of the Complaint.

18 **Response to Fourth Cause of Action: Implied Warranty**

19 47. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
20 Complaint as if fully set forth herein.

21 48. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
28 Celebrex® is defective, and deny the remaining allegations this paragraph of the Complaint.

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1 49. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
3 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations this paragraph of the Complaint.

9 50. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
10 damages, and deny the remaining allegations this paragraph of the Complaint.

Response to Fifth Cause of Action: Unjust Enrichment

12 51. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
13 Complaint as if fully set forth herein.

14 52. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
15 damages, and deny the remaining allegations this paragraph of the Complaint.

Response to Allegations Regarding Damages

17 53. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
18 Complaint as if fully set forth herein.

19 54. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
20 damages, and deny the remaining allegations this paragraph of the Complaint, including all
21 subparts.

22 55. Answering the unnumbered paragraph following Paragraph 54 of the Complaint,
23 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
24 damages, and deny the remaining allegations this paragraph of the Complaint, including all
25 subparts.

III.

GENERAL DENIAL

28 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs'

Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs' damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs are not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’

treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Celebrex® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

1 **Twentieth Defense**

2 20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are
 3 preempted in accordance with the Supremacy Clause of the United States Constitution and by
 4 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

5 **Twenty-first Defense**

6 21. Plaintiffs' claims are barred in whole or in part under the applicable state law because
 7 the subject pharmaceutical product at issue was subject to and received pre-market approval by
 8 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

9 **Twenty-second Defense**

10 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
 11 Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes,
 12 and Plaintiffs' causes of action are preempted.

13 **Twenty-third Defense**

14 23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary
 15 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
 16 issue under applicable federal laws, regulations, and rules.

17 **Twenty-fourth Defense**

18 24. Plaintiffs' claims are barred in whole or in part because there is no private right of
 19 action concerning matters regulated by the Food and Drug Administration under applicable
 20 federal laws, regulations, and rules.

21 **Twenty-fifth Defense**

22 25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate
 23 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning
 24 of Comment j to Section 402A of the Restatement (Second) of Torts.

25 **Twenty-sixth Defense**

26 26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim
 27 because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of
 28 Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitution of the States of California and Arkansas, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitution of the States of California and Arkansas. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5)

permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

10 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
11 and marketing of Celebrex®, if any, used in this case, included adequate warnings and
12 instructions with respect to the product's use in the package insert and other literature, and
13 conformed to the generally recognized, reasonably available, and reliable state of the
14 knowledge at the time the product was marketed.

Fortieth Defense

16 40. The claims asserted in the Complaint are barred because Celebrex® was designed,
17 tested, manufactured and labeled in accordance with the state-of-the-art industry standards
18 existing at the time of the sale.

Forty-first Defense

20 41. If Plaintiffs sustained injuries or losses as alleged in the Complaint, upon information
21 and belief, such injuries and losses were caused by the actions of persons not having real or
22 apparent authority to take said actions on behalf of Defendants and over whom Defendants had
23 no control and for whom Defendants may not be held accountable.

Forty-second Defense

25 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
26 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
27 intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

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1

Fiftieth Defense

2 50. Plaintiffs' damages, if any, are barred or limited by the payments received from
3 collateral sources.

4

Fifty-first Defense

5 51. Defendants' liability, if any, can only be determined after the percentages of
6 responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if
7 any, are determined. Defendants seek an adjudication of the percentage of fault of the
8 claimants and each and every other person whose fault could have contributed to the alleged
9 injuries and damages, if any, of Plaintiffs.

10

Fifty-second Defense

11 52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the
12 common law gives deference to discretionary actions by the United States Food and Drug
13 Administration under the Federal Food, Drug, and Cosmetic Act.

14

Fifty-third Defense

15 53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
16 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
17 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs'
18 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
19 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
20 and with the specific determinations by FDA specifying the language that should be used in the
21 labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the
22 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
23 United States.

24

Fifty-fourth Defense

25 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity
26 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

27

Fifty-fifth Defense

28 55. Defendants state on information and belief that the Complaint and each purported cause

of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as may apply.

Fifty-sixth Defense

5 56. Defendants state on information and belief that any injuries, losses, or damages suffered
6 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable
7 conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against
8 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

10 57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of
11 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
12 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
13 damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

15 58. Plaintiffs' fraud based claims, if any, are not stated with particularity as required by
16 Rule 9 of the Federal Rules of Civil Procedure and/or Rule 9 of the Arkansas Rules of Civil
17 Procedure.

Fifty-ninth Defense

19 59. Plaintiffs' damages, if any, must be reduced by the percentage of fault attributable to
20 Plaintiffs and to nonparties as provided by Ark. Code Ann. § 16-55-202.

Sixtieth Defense

22 60. Plaintiffs' claims are barred and/or limited by the provisions of the Arkansas Products
23 Liability Act, Ark. Code Ann. § 16-116-101, et seq.

Sixty-first Defense

25 61. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Arkansas
26 Civil Justice Reform Act of 2003, Ark. Code Ann. § 16-55-201, et seq.

Sixty-second Defense

28 | 62. Defendants reserve the right to supplement their assertion of defenses as they continue

with their factual investigation of Plaintiffs' claims.

V.

PRAAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
 2. That the Complaint be dismissed;
 3. That Defendants be awarded their costs for this lawsuit;
 4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;
 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and
 6. That Defendants have such other and further relief as the Court deems appropriate.

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1 May 30, 2008

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10 May 30, 2008

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21 LLC

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

May 30, 2008

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